TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
C1-A0308P		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/014207	29.09.2004	29.09.2003

International Patent Classification (IPC) or national classification and IPC

C12N15/09 A61K45/00 A61P1/16 A61P11/06 A61P31/12 A61P31/14 A61P35/00 A61P37/04

Applicant

CHUGAI SEIYAKU KABUSHIKI KAISHA

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 11 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☒ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      1 disk , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 11-13,15-18

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 11-13, 15-18
are so unclear that no meaningful opinion could be formed (*specify*):

With regards to the ligands, the agonists and the antagonists that are set forth in claims 11 to 13 and 15 to 18, it was impossible to find any ligand, agonist or antagonist that is fully supported by the description in the meaning of PCT Article 6 or disclosed in the description in the meaning of PCT Article 5.

☒ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 11-13,15-18

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
   - ☐ restricted the claims.
   - ☐ paid additional fees.
   - ☐ paid additional fees under protest.
   - ☐ neither restricted the claims nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
   - ☐ complied with.
   - ☒ not complied with for the following reasons:

The proteins that comprise an amino acid sequence represented by either SEQ ID NO: 2 or SEQ ID NO: 4 set forth in claim 1 and the proteins that comprise the amino acid sequence represented by SEQ ID NO: 6 set forth in claim 1 do not have a novel chemical structure in common, and are only linked by the fact that said proteins are NK cell receptor proteins. However, NK cell receptor proteins were well known prior to the priority date of the present application, as disclosed in the document JP 2003-527105 A, and thus the feature of being a NK cell receptor protein cannot be said to be a special technical feature as defined in PCT Rule 13.2.

[Refer to the Supplemental Box]

4. Consequently, this report has been established in respect of the following parts of the international application:
   - ☐ all parts.
   - ☒ the parts relating to claims Nos. 1-10,14,19,20

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	8-10, 14, 19, 20	YES
	Claims	1-7	NO
Inventive step (IS)	Claims		YES
	Claims	1-10, 14, 19, 20	NO
Industrial applicability (IA)	Claims	1-10, 14, 19, 20	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: EP 1201681 A

The inventions set forth in claims 1 to 7 lack novelty in the light of document 1 cited in the international search report. Document 1 discloses various receptor proteins that are collectively referred to as 'FAIL' proteins, the DNAs that encode said proteins, vectors and host cells that include said DNAs, and antibodies for binding said proteins. Therein, the FAIL proteins that are represented by SEQ ID NO: 6 and 34 correspond to fragments of the proteins that comprise the amino acid sequence represented by SEQ ID NO: 4 set forth in the present application and fragments of the proteins that comprise the amino acid sequence represented by SEQ ID NO: 2 set forth in the present application; therefore, the DNAs that encode the proteins in question can be said to be capable of hybridizing with DNA that comprises the base sequence represented by SEQ ID NO: 1 set forth in the present application and DNA that comprises the base sequence represented by SEQ ID NO: 3 set forth in the present application under stringent conditions. As a result, document 1 can be said to disclose the DNAs that are set forth in claim 1 (d) and claim 2 as well as the

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

proteins that are set forth in claim 3, and thus document 1 can also be considered to disclose the vectors, the host cells and the antibodies that are set forth in claims 4 to 7.

In addition, it is common practice for a person skilled in the art to search for the ligands, the agonists and the antagonists that are associated with a receptor protein; likewise, it is also common practice for a person skilled in the art to configure a probe for detecting the DNA that encodes a receptor protein by producing a strand of at least 15 nucleotides which is complimentary to said DNA. Such being the case, the inventions set forth in claims 8 to 10, 14, 19 and 20 could easily have been invented by a person skilled in the art in the light of the disclosures in document 1.

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Box No. VI **Certain documents cited**

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 03/89624 A [E, X]	30.10.2003	25.03.2003	25.03.2002

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

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Box No. VIII **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The disclosure "functionally similar" in claim 1 does not clearly specify either the function that is supposed to be similar or the manner in which said function is similar, and thus the scope of the invention that is set forth in claim 1 is unclear.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purposes of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

* *If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."*

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

The Cover Sheet.

International Patent Classification (IPC) or national classification and IPC: Int.Cl.[7]

A61P 37/06 A61P 37/08 C07K 14/705 C07K 16/28
C12N1/15C12N1/19 C12N 1/21 C12N 5/00 C12P 21/02 C12Q 1/02
GO1N 33/15 GO1N 33/50

Supplemental Box

Box IV

Such being the case, there cannot be said to be a technical relationship involving one or more of the same or corresponding special technical features which links the inventions pertaining to proteins that comprise an amino acid sequence represented by either SEQ ID NO: 2 or SEQ ID NO: 4 set forth in claim 1 and the inventions pertaining to proteins that comprise the amino acid sequence represented by SEQ ID NO: 6 set forth in claim 1 among the inventions that are set forth in claims 1 to 20, and thus the inventions in question cannot be said to be linked so as to form a single general inventive concept.

Consequently, the present international application does not conform to the requirements of unity of invention.